



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/578,602

05/08/2006

Steffen Hardt

FMW-CP-PCT-US

6981

28862 7590 11/29/2010
HUDAK, SHUNK & FARINE, CO., L.P.A.
2020 FRONT STREET
SUITE 307
CUYAHOGA FALLS, OH 44221

EXAMINER

DIETERLE, JENNIFER M

ART UNIT

PAPER NUMBER

1759

MAIL DATE

DELIVERY MODE

11/29/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/578,602	Applicant(s) HARDT, STEFFEN	
	Examiner Jennifer Dieterle	Art Unit 1759	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,6,12,13 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,6,12,13 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 September 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

This case was part of the First Office Action Pilot Program. Applicant filed a request not to have a first action interview and a First Action Interview Office Action Summary was mailed on September 1, 2010 (Form PTOL-413FA). Applicant then requested an interview which was conducted on October 14, 2010; however, no agreement was reached. This action is in response to applicant's amendment filed September 10, 2010 and is being made FINAL.

Claim 19 was added by amendment.

Claims 4, 6, 12, 13 and 19 are pending.

Comments

1. The objection to Figure 1a is withdrawn due to applicant's drawing amendments filed September 10, 2010.

Response to Amendment

2. Applicant's amendment dated September 10, 2010 does not render the application allowable. Applicant's arguments with respect to claims 4, 6, 12 and 13 have been considered but are not persuasive. Given the broad claim language of claim

Art Unit: 1759

4, the 103(a) rejection utilizing Dantsker is maintained. Additionally, due to applicant's amendments, an additional rejection utilizing the previously cited prior art of record, Oakey et al. (US 2003/0159999), is set forth below.

3. Regarding applicant's remarks concerning the 35 U.S.C. 112 second paragraph rejections. Per the telephone interview, the examiner was able to gain a better understanding of applicant's invention. Applicant's attorney, Mr. Hudak, clarified that the liquid/gel is moving through the device and the particles of interest are also moved through the device. Mr. Hudak pointed to figures 7a and b as being indicative of the invention being claimed. It was noted by the examiners that the figures did not appear to correlate to the claimed invention and appeared to be very different concepts from each other which made this particular application very difficult to understand. For example figures 1-4 appear to contain only two channels and that the fluid is being moved utilizing electric force. Figures 5 and 6 are still not clearly understood. Additionally, it did not appear that there was a preferred embodiment for reference to the claims in order to facilitate an understanding of the invention.

4. Mr. Hudak noted that there are no spacers or separators between the liquid/gel lamellae. If there are no separators between the liquid/gel lamellae, it is not clear how a liquid (even different phases) would remain in their separate lamellae given the forces exerted on the liquid as it moves through the device. One skilled in the art would note that the liquid would intermix/disperse into one another and given the flow of the liquid, one skilled in the art would expect the fluid to experience turbulence when it exits the

Art Unit: 1759

entry ports and that a portion of each lamellae would disrupt adjacent lamellae.

Additionally, if gel was selected, it is not clear how gel would be moved through the device given that a gel can be a viscous substance which may not be inclined to move.

5. Additionally, during the interview, Mr. Hudak clarified, that in claim 4, it is the electric field that is applied perpendicular to the phase boundaries, not the different phases are perpendicular.

6. Regarding applicant's remarks concerning Dantsker disclosing a passive control of fluid flow, as currently written, claim 4 does not require the application of an electric field to promote fluid flow through the device. As noted by Mr. Hudak, claim 4's electric field is referring to a field perpendicular to the lamellae. Therefore, there is nothing in claim 4 that would require an activated fluid flow and thus would appear that the claim can read on passive fluid flow (see applicant's figure 7, section 0051, showing only one pair of electrodes for perpendicular electric field, thus it would appear to be a passive flow through the claimed invention).

7. Additionally, all that is required of claim 4 is a plurality (i.e. which can be 2 or more) of adjoining liquid or gel lamellae of two or more different phases. Dantsker provides for the use of sol-gel which can be of different phases (sections 0060-61) in which they are adjoining (see figure 2b or 3b showing a plurality of adjoining channels). Therefore, it would appear that Dantsker reads on claim 4 as written except for the application of a perpendicular electric field. The Manach reference was cited to show that the application of perpendicular electric fields for separation is known in the art and utilized by one skilled in the art in order to perform separation (section 0074). While

Art Unit: 1759

applicant notes that the phases in Manach are sorbents and not liquids, this is not relevant. What is relevant is that Manach clearly show that perpendicular electric fields can be applied to a plurality of channels either simultaneously or sequentially with respect to the separation movement in order to promote further separation of the fluid in the channels. Therefore, one skilled in the art would have been motivated to apply an electric field perpendicular to the phases in Dantsker as taught by Manach because it is known in the separation art that the application of a perpendicular electric field will promote further separation of particles.

8. It is also noted that Oakey et al. (US 2003/0159999) was cited as prior art that also teaches the application of an electric field perpendicular to the fluid flow in which there are two phases. Oakey et al. teach a microfluidic device in which a first fluid 152 and the second fluid 154 (figure 6, section) flow through the microfluidic flow chamber in a laminar manner.

Claim Objections

9. Claim 1 is objected to because of the following informalities: “Llamellae” is spelled incorrectly in claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1759

10. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The present method provides for the use of a device in which a plurality of adjoining liquid/gel lamellae are adjoining and that the liquid/gel is moving through the device and the particles of interest are also moved through the device.

During the telephone interview, Mr. Hudak noted that there are no spacers or separators between the liquid/gel lamellae. If there are no separators between the liquid/gel lamellae, it is not clear how a liquid (even different phases) would remain in their separate lamellae given the forces exerted on the liquid as it moves through the device. One skilled in the art would note that the liquid would intermix/disperse into one another and given the flow of the liquid, one skilled in the art would expect the fluid to experience turbulence when it exits the entry ports and that a portion of each lamellae would disrupt adjacent lamellae. Additionally, if gel was selected, it is not clear how gel would be moved through the device given that a gel can be a viscous substance which may not be inclined to move and it is also noted that there is no electric field to induce movement across (i.e. from entry to exit) of the microfluidic system (i.e. no electrodes in the preferred invention figure 7b to induce flow). Since claim 4 is rejected, so too are dependent claims 6, 12, 13 and 19.

11. Claim 4 is also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 notes "applying an electric field" and "two or

Art Unit: 1759

more different phases". Claim 4 proceeds to specify "perpendicular to the phase boundaries". It is not clear whether it is the electric field that is applied perpendicular to the phase boundaries or whether the different phases are perpendicular. During a telephone interview, Mr. Hudak noted that it is the electric field that is perpendicular to the phase boundaries. Claim 4 should be rewritten to clearly express this limitation. Since claim 4 is rejected, so too are dependent claims 6, 12, 13 and 19.

12. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what is being claimed in claim 12. Claim 12 appears to be referencing two substances; however, claim 4 only references the separation of a chemical substance/particle. It is not clear whether claim 12 is referring to the phases of the substance being separated or an entirely separate substance being added to the device. It is also not clear what is meant by "adjusted in the phases". It is not clear what force is being applied that would allow for any "adjustment in the phases" or what exactly is the adjustment that is happening. The unclear nature of claim 12 makes it difficult to examine and to present a rejection, claim 12 is being interpreted as an additional additive is added to the phase to create a binding event with the particle to promote further separation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1759

13. Claims 4, 6, 12, 13 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Dantsker et al. (US 2002/0153046) in view of Manach et al. (2004/0104173)**.

Regarding claim 4, Dantsker et al. teach a microfluidic device that utilizes a sol-gel that can comprise two phases (section 0060) that can be arranged in parallel in a plurality of channels (see figure 2b, 45,46,47 and 3b, 76,62,60 or 5b, 112 - showing plurality of channels).

Dantsker et al. does not specifically teach the application of an electric phase.

Manach et al. teach an electrochromatic device in which electric fields can be applied in either parallel or perpendicular (section 0074) to the laminar flow of fluids.

Therefore, one skilled in the art would have been motivated to apply an electric field perpendicular to the phases in Dantsker as taught by Manach because it is known in the separation art that the application of a perpendicular electric field will promote further separation of particles.

Regarding claims 6 and 13, Dantsker et al. teach that the device comprises microfluidic channels less than about 500 microns parallel arranged; thus, the thickness would be submillimeter (section 0011 and figure 2 and 3).

Regarding claim 12, Dantsker et al. teach a microfluidic device, but does not teach that the particle has an affinity for the phase.

Manach et al. teach the use of a ligand or antibody to create a hybridization event to aid in separation and analysis (section 0096).

Therefore, it would have been obvious to one skilled in the art to include an affinity molecule such as an antibody or ligand in the channels of Dantsker et al. that will bind with the particle of interest or bind particles that are not of interest allowing the particle of interest to be separated as taught by Manach et al.

14. Claims 4, 6, 12, 13 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Oakey et al. (US 2003/0159999 A1)**.

Regarding claims 4 and 19, as previously noted, Oakey et al. a microfluidic device comprising flow channels which contain a first fluid 152 and a second fluid 154 which can be two different phases (figure 6, section 0062-65, laminar two-phase flow may be used as an effective barrier against particle cross-transport). Oakey et al. also teach the application of an electric field perpendicular to the fluid flow to move a particle 156 from one stream to another stream.

Although Oakey et al. does not disclose a plurality of adjoining lamellae of two different phases, the court held that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced. See *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960); MPEP 2144.04 VI B.

Therefore, it would have been obvious to one skilled in the art to duplicate the first and second fluid 152/154 in Oakey et al. to promote separation, yet still result in the movement and separation of a particle and would not produce a new or unexpected

Art Unit: 1759

result. It is also noted that applicant's figure 1 depicts a similar flow channel as that of Oakey et al. in which there are two phases. Applicant also depicts a flow channel in figure 7 with a plurality of these phases. There is no documentation in applicant's specification that would lead one skilled in the art to believe that the channels of figure 1 and 7 would provide a different result.

Regarding claims 6 and 13, Oakey et al. teach that each phase 152 and 154 have a width of about 30 micrometers (i.e. 0.03 millimeters = submillimeter)(section 0062). Therefore, both phases 152 and 154 together would only have a width of about 60 micrometers or 0.06 millimeters. Oakey et al. teach that the phases are arranged in parallel (see figure 6).

Regarding claim 12, since it is entirely unclear what is being claimed in claim 12, claim 12 is being examined as though there is an additional substance added to the flow which has an affinity for the particles being separated. Given this interpretation, Oakey et al. teach a microfluidic device comprising laminar flow channels in which the suspension may be pretreated with an antibody that will bind specifically to a particular type of particle may be used to enable or enhance the recognition of the particle (section 0048).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 1759

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dieterle whose telephone number is (571) 270-7872. The examiner can normally be reached on Monday thru Thursday, 9am to 4pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alexa Neckel can be reached on (571) 272-1446. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1759

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JMD

11/11/10

/Alexa D. Neckel/

Supervisory Patent Examiner, Art Unit 1723